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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LEAVITT, MARIA GOMEZ	
ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,349	TAMAMAKI, NOBUAKI	
	Examiner	Art Unit	
	MARIA LEAVITT	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-16* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

I. Claims 1 and 5-13, drawn to an *in vitro* method for separating a precursor cell producing a GABAergic neuron alone comprising introducing a DNA, in which a cDNA of a reporter protein emitting a signal detectable even *in vivo* is attached to the downstream of a promoter of GAD67 gene or GAD65 gene that is gene of an inhibitory neurotransmitter GABA synthase, into each cell in the cell population and isolating a GABAergic neuron and a precursor cell of GABAergic neuron based on the presence/ absence of the signal emitted by the reporter.

II. Claims 1, 5-13 and 14 drawn to an *in vivo* method for separating a precursor cell producing a GABAergic neuron alone comprising introducing a DNA, in which a cDNA of a reporter protein emitting a signal detectable even in vivo is attached to the downstream of a promoter of GAD67 gene or GAD65 gene that is gene of an inhibitory neurotransmitter GABA synthase, into each cell in the cell population and isolating a GABAergic neuron and a precursor cell of GABAergic neuron based on the presence/ absence of the signal emitted by the reporter and further transplanting the cell separated into a recipient .

III. Claims 2 and 5-13, drawn to an *in vitro* method for separating a precursor cell producing a GABAergic neuron alone introducing a DNA, in which a cDNA of a protein imparting a property of drug resistance is attached to the downstream of a promoter of GAD67 gene

or GAD65 gene that is gene of an inhibitory neurotransmitter GABA synthase, into each cell in the cell population and isolating a GABAergic neuron and a precursor cell of GABAergic neuron based on the presence/absence of the drug resistance.

IV. Claims 2 and 5-13 and 14 drawn to an *in vivo* method for separating a precursor cell producing a GABAergic neuron alone introducing a DNA, in which a cDNA of a protein imparting a property of drug resistance is attached to the downstream of a promoter of GAD67 gene or GAD65 gene that is gene of an inhibitory neurotransmitter GABA synthase, into each cell in the cell population and isolating a GABAergic neuron and a precursor cell of GABAergic neuron based on the presence/absence of the drug resistance and further transplanting the cell separated into a recipient .

V. Claims 3 and 5-13, drawn to an *in vitro* method for separating a precursor cell producing a GABAergic neuron alone comprising introducing a DNA, in which a cDNA of a recombinant enzyme and a cassette DNA are attached to the downstream of a promoter of GAD67 gene or GAD65 gene that is a gene of an inhibitory neurotransmitter GABA synthase, into each cell in the cell population, wherein the cassette DNA expresses a reporter protein emitting a signal detectable even in vivo after being genetically recombined and isolating a GABAergic neuron and a precursor cell of GABAergic neuron based on the presence/absence of the signal emitted by the reporter.

VI. Claims 3, 5-13 and 14, drawn to an *in vivo* method for separating a precursor cell producing a GABAergic neuron alone comprising introducing a DNA, in which a cDNA of a recombinant enzyme and a cassette DNA are attached to the downstream of a promoter of GAD67 gene or GAD65 gene that is a gene of an inhibitory neurotransmitter

GABA synthase, into each cell in the cell population, wherein the cassette DNA expresses a reporter protein emitting a signal detectable even in vivo after being genetically recombined and isolating a GABAergic neuron and a precursor cell of GABAergic neuron based on the presence/absence of the signal emitted by the reporter and further transplanting the cell separated into a recipient .

VII. Claims 4 and 5-13, drawn to an *in vitro* method for separating a precursor cell producing a GABAergic neuron alone comprising a DNA, in which a cDNA of a recombinant enzyme and a cassette DNA are attached to the downstream of a promoter of GAD67 gene or GAD65 gene that is gene of an inhibitory neurotransmitter GABA synthase, into each cell in the cell population, wherein the cassette DNA expresses a protein imparting a property of drug resistance after being genetically recombined; (c) isolating a GABAergic neuron and a precursor cell of GABAergic neuron based on the presence/absence of the drug resistance.

VIII. Claims 4, 5-13 and 14, drawn to an *in vivo* method for separating a precursor cell producing a GABAergic neuron alone comprising a DNA, in which a cDNA of a recombinant enzyme and a cassette DNA are attached to the downstream of a promoter of GAD67 gene or GAD65 gene that is gene of an inhibitory neurotransmitter GABA synthase, into each cell in the cell population, wherein the cassette DNA expresses a protein imparting a property of drug resistance after being genetically recombined; (c) isolating a GABAergic neuron and a precursor cell of GABAergic neuron based on the presence/absence of the drug resistance and further transplanting the cell separated into a recipient.

IX. Claim 15 drawn to a precursor cell producing a GABAergic neuron alone.

X. Claim 16 drawn to A kit containing a reagent and a cell, which is used for obtaining a precursor cell producing a GABAergic neuron alone.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons:

37 CFR 1.475 (c) states:

"If an application contains to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present"

37 CFR 1.475 (d) also states:

"If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c)".

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons: the technical feature linking groups I-X appears to be that they all relate to a method for separating a precursor cell of GABAergic neuron in an adult or a fetal nerve tissue derived from an embryo stem cell and further transplanting precursor cells of GABAergic neurons into a recipient. However, prior art has taught the use of neural cells derived from mouse ES cells to express mRNAs characteristic of GABAergic neurons wherein the glutamate decarboxylase genes (*Gad1* and *Gad2*), required for GABA synthesis and the vesicular

inhibitory amino acid transporter (*Viaat*) gene, required for GABA vesicular packaging are activated in the ES-derived cultures and, further, ES-derived neurons are selected based on the expression of the GAD67 protein (Westmoreland et al., Biochemical and Biophysical Research Communications, 2001, Pages 674-680).Therefore, the technical feature linking the invention of Groups I-X does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over prior art for the reasons set forth above.

The inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Inventions of Groups I-X are drawn to materially different and distinct inventive concepts, having different chemical structures, physical properties and biological functions. Inventions of Groups I, III, V and VII are drawn to in *vitro* methods for separating a precursor cell of GABAergic neuron whereas inventions of Groups II, IV, VI and VIII are drawn to in *vivo* therapy methods comprising transplanting the cell separated into a recipient which is not required by the active steps of Groups I, III, V and VII. For example inventions of Groups II, IV, VI and VIII required the step of administering to a patient suffering from GABAergic neuronal decreased in the brain a precursor cell of GABAergic neuron which step is not required by the inventions of Groups I, III, V and VII. In addition, each of the inventions of Groups I, III, V and VII require unique steps not required by any other group. For example, Group III and IV require the steps of introducing a cDNA of a protein imparting a property of drug resistance and isolating a precursor cell of GABAergic neuron based on the presence/absence of the drug resistance not disclosed as being required for groups I, II, V,VI,VII or VII. Moreover, inventions

of Group IX drawn to a precursor cell producing a GABAergic neuron alone include unique technical features that are not shared by the inventions of Groups I-VII or X. Further, inventions claimed by Group X are drawn to a product kit to prepare *in vitro* a precursor cell of GABAergic neuron not required by any of the Groups I-IX. .

Thus, the claims in Groups I-X are drawn to distinct products and methods that utilize distinct steps, requiring non-coextensive search and examination. Hence, it follows from the preceding analysis that the claimed inventions listed as Groups I-X do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the reasons set forth above.

MPEP 1893.03(d) states:

If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined. See MPEP § 821.04 and § 821.04(a). Any nonelected processes of making and/or using an allowable product should be considered for rejoinder following the practice set forth in MPEP § 821

Species restriction

Should **Group I-VIII** be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated

above. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

1) an embryo stem cell or a neural stem cell, dispersing tissues containing a precursor cell of GABAergic neuron of a donor, as recited in claims 5 and 6 .

The species are independent or distinct because there are methods of preparing cell populations having different chemical structures, physical properties, and biological functions as the result of comprising distinct active steps.

2) transformation mediated by a virus, transformation mediated by a electroporation, transformation mediated by a liposome, as recited in claims 7, 8 and 9 .

The species are independent or distinct because there are methods of transformation having different chemical structures, physical properties, and biological functions as the result of comprising distinct active steps.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As the technical feature of a sequence coding for a polypeptide, linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature, the requirement for unity of invention is not fulfilled.

Applicant is required, in reply to this action, to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1 and 13 are generic.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/Maria Leavitt/

Maria Leavitt, Ph.D.
Examiner, Art Unit 1633